**510(k )Summary**

**FG-36UX, Fiber Ultrasound Gastroscope for use with EUB-6000 Ultrasound Diagnostic Scanner**

K010740

**Submitter Information:**

APR 1 7 2001

Pentax Precision Instrument Corporation (PPIC)
30 Ramland Road
Orangeburg, NY, 10962
Tel: (914)-365-0700

**Name Of Device:** Trade Name: FG-36UX, Fiber Ultrasound Gastroscope
Classification Name: Diagnostic Ultrasound Transducer (74JOP) {892.1570}, Endoscope and Accessories (78KOG) {876.1500}

**Predicated Device(s) Information:**

| Model, Description | Manufacturer | PMN# |
|---|---|---|
| FG-36UX, Fiber Ultrasound Gastroscope (with EUB-410,-515,-565,-555) | PPIC | K961974 |
| EUB-6000, Ultrasound Diagnostic Scanner | Hitachi America | K994026 |

**Device Description:** The FG-36UX, Fiber Ultrasound Gastroscope, can be used with any Lightsource (with the appropriate lightguide receptacle) and must be used with Ultrasound Scanner (software controlled device). The endoscope has a flexible insertion tube, a control body, and Umbilicus . The umbilicus is bifurcated where one connector is connected to the Lightsource and contains connections for air/water and suction. The other umbilicus bifurcation is connected at the ultrasound scanner. The control body includes controls for up/ down/ left/ right angulation, an accessory elevator control, air/water delivery, suction selection/ control, forward water jet port, balloon insulflation, an accessory inlet port, and the endoscopic image viewing occular. The device contains light carrying bundles, one to illuminate the body cavity another to optically visualize the anatomy, and an ultrasound transducer to collect ultrasonic image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced (the instrument is supplied with two biopsy forceps). A convex linear array transducer delivers ultrasonic pulses, reflections of the pulses are received and signals are passed to the Ultrasound Scanner for display. The instrument is immersable (with the use of supplied cleaning accessories) except for the Ultrasound Scanner Connector (as described in the Endoscope operator Manual cleaning instructions).

**Intended Use:** The FG-36UX, Fiber Ultrasound Gastroscope, is intended to provide optical visualization of , ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

**Comparison To Predicated Device(s):**
The submission for substantial equivalence included FG-36UX literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices in summary. The submission for substantial equivalence was not based on an assessment of clinical performance data.

**Prepared by**: Paul Silva Signature: Paul Silva Date: 03.09.01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 7 2001

Mr. Paul Silva
Regulatory Affairs Coordinator
Pentax Precision Instrument Corporation
30 Ramland Road
ORANGEBURG NY 10962-2699

Re: K010740
Trade Name: FG-36UX Fiber Ultrasound Gastroscope/
EUB-6000 Ultrasound Diagnostic Scanner
Regulatory Class: II/21CFR892.1550/21CFR876.1500
Product Code: 90 IYN/78 KOG
Dated: March 12, 2001
Received: March 13, 2001

Dear Mr. Silva:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-6000 Ultrasound Diagnostic Scanner, as described in your premarket notification:

Transducer Model Number

FG-36UX

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

*Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. (This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.") If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

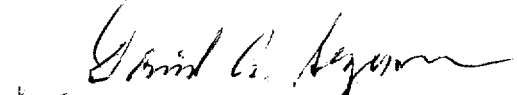
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE

System: EUB-6000

Probe: FG-36UX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

| Clinical Application | | Mode of Operation | | | | | |
|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Track I & III) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler |
| Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | |
| | Abdominal | | | | | | |
| | Intra-operative (Spec.) | | | | | | |
| | Intra-operative (Neuro.) | | | | | | |
| | Laproscopic | | | | | | |
| | Pediatric | | | | | | |
| | Small Organ | | | | | | |
| | Neonatal Cephalic | | | | | | |
| | Adult Cephalic | | | | | | |
| | Trans-rectal | | | | | | |
| | Trans-vagina | | | | | | |
| | Trans-urethral | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | |
| | Intra-luminal | | | | | | |
| | Endoscopy | N | N | N | | N | N |
| Cardiac | Cardiac Adult | | | | | | |
| | Cardiac Pediatric | | | | | | |
| | Trans-esophageal (card.) | | | | | | |
| | Other (spec.) | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | |
| | Other (Spec.) | | | | | | |

N = new application: P = previously cleared by FDA: E = added under Appendix E

(Please do not write below this line – continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010740